UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,719	01/13/2004	Mark E. Cook	960296.00108	2648

27114 7590 03/06/2007

QUARLES & BRADY LLP
411 E. WISCONSIN AVENUE, SUITE 2040
MILWAUKEE, WI 53202-4497

EXAMINER	
ARNOLD, ERNST V	
ART UNIT	**PAPER NUMBER**
1616	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/756,719	COOK ET AL.	
	Examiner	Art Unit	
	Ernst V. Arnold	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/28/06 has been entered.

Claims 1-16 are pending.

Withdrawn rejections:

Claims 1-13 were rejected under 35 U.S.C. 102(b) as being anticipated by Menard et al. (WO 02/09725). Applicant has amended claim 1 to recite "consists of" and Menard et al. do not meet this limitation and the Examiner is withdrawing the rejection.

Claims 1-5 and 7-12 were rejected under 35 U.S.C. 102(b) as being anticipated by Horrobin et al. (US 6,245,811). Applicant has amended claim 1 to recite "and one or more carriers" and Horrobin et al. do not meet this limitation and the Examiner is withdrawing the rejection.

Claims 1-16 were rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (US 6,077,868) in view of Watkins et al. (Journal of the American College of Nutrition 2000, 19(4), 478S-486S). Applicant's arguments are deemed persuasive and the Examiner is withdrawing the rejection in favor of the one below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 4-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating rheumatoid arthritis by administering conjugated linoleic acid, does not reasonably provide enablement for treating all diseases or conditions caused by type III hypersensitive reactions in a human or non-human animal with conjugated linoleic acid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims without an undue amount of experimentation.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: 1) scope or breadth of the claims; 2) nature of the invention; 3) relative level of skill possessed by one of ordinary skill in the art; 4) state of, or the amount of knowledge in, the prior art; 5) level or degree of predictability, or a lack thereof, in the art; 6) amount of guidance or direction provided by the inventor; 7) presence or absence of working examples; and 8) quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are weighed, it is the Examiner's position that one skilled in the art could not practice the invention without undue experimentation.

1) <u>Scope or breadth of the claims</u>

The claims are broader in scope than the enabling disclosure. The specification merely discloses, without more, that conjugated linoleic acid can be used in the murine model of rheumatoid arthritis (Pages 5-6, Example). However, Applicant is purporting to treating all diseases or conditions caused by type III hypersensitive reactions in a human or non-human animal with conjugated linoleic acid.

2) Nature of the invention

The nature of the invention is directed to treatment of arthritis with conjugated linoleic acid.

3) Relative level of skill possessed by one of ordinary skill in the art

The relative level of skill possessed by one of ordinary skill in the art of medical research is relatively high, as a majority of lead investigators directing scientific research and development in this particular technological area possess an M.D. and/or a Ph.D. in a scientific discipline such as organic synthetic chemistry, medicinal chemistry, biochemistry, pharmacology, biology or the like.

4) State of, or the amount of knowledge in, the prior art

The art teaches that methods of administering conjugated linoleic acid to humans or non-human animals having a disease characterized by autoimmune complexes such as rheumatoid arthritis and lupus (Cook et al. US 6,395,782 claims 1-11; for example).

5) Level or degree of predictability, or a lack thereof, in the art

6) Amount of guidance or direction provided by the inventor

Applicant was required to provide in the specification additional guidance and direction with respect to how use the claimed subject matter in order for the application to be enabled with

respect to the full scope of the claimed invention. Although the instant specification discloses a method for treating rheumatoid arthritis with conjugated linoleic acid, it remains silent on treating all diseases or conditions caused by type III hypersensitive reactions in a human or non-human animal with conjugated linoleic acid.

7) Presence or absence of working examples

The specification fails to provide scientific data and working embodiments with respect to treating all diseases or conditions caused by type III hypersensitive reactions in a human or non-human animal with conjugated linoleic acid.

8) Quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure

One of ordinary skill in the art would have to conduct a myriad number of time consuming clinical experiments with animal models and/or patients comprising administering conjugated linoleic acid to patients suffering from debilitating diseases where failure of the treatment results in increased patient suffering. As a result, one of ordinary skill in the art would be required to conduct an undue amount of experimentation to reasonably and accurately determine whether treating all diseases or conditions caused by type III hypersensitive reactions in a human or non-human animal with conjugated linoleic acid would work.

Genetech, 108 F.3d at 1366 states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (US 6,395,782) in view of Horrobin et al. (US 6,245,811).

Applicant claims a method of treating rheumatoid arthritis by administering conjugated linoleic acid.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Cook et al. teach methods of extending the survival time of a human or non-human animal having a disease, thus in need of treatment, characterized by autoimmune complexes by administering an effective amount of conjugated linoleic acid (Claim 1). Cook et al. teach isomers of conjugated linoleic acid (column 4, lines 40-45). Cook et al. teach methods suitable for treating rheumatoid arthritis (column 3, lines 37-60). Cook et al. teach feeding, thus oral

administration, mice diets of conjugated linoleic acid and corn oil (column 4, lines 49-54). It is the Examiner's position that corn oil can serve as a carrier. Cook et al. teach conjugated linoleic acid in the range of about 0.05% to about 2.0% in the diet or about 0.1 to 10g/day (column 4, lines 15-20).

Horrobin et al. teach and suggest a method for treating a disorder (rheumatoid arthritis) comprising administering to a patient in need thereof an effective amount of the compound according to claim 1 where R_1 is an acyl moiety corresponding to an acid (conjugated linoleic acid) (Column 14 lines 55-62; column 15, line 1 and claims 1, 10 and 28). The Examiner interprets the compound to be an ester of conjugated linoleic acid. Doses may be administered to the patient in need thereof orally, enterally, topically, parenterally, (subcutaneously, intramuscularly, intravenously), rectally, vaginally or by any other appropriate route (Column 17, lines 32-36 and claim 28). By patient, the Examiner interprets this to be a human. Horrobin et al. teach that the compound can be in a food or nutritional supplement (Claim 40).

Horrobin et al. disclose in claim 28 a method of treating a disorder selected from the group consisting of...rheumatoid arthritis...comprising administering to a patient in need thereof an effective amount of the compound of claim 10. Horrobin et al. disclose in claim 10 a compound according to claim 1 where R1 is an acyl moiety corresponding to...conjugated linoleic acid. Therefore, it is the Examiner's position that Horrobin et al. teach or suggest a method of treating rheumatoid arthritis with a compound containing conjugated linoleic acid.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Cook et al. do not expressly teach a method wherein the conjugated linoleic acid is an ester of a conjugated linoleic acid.

Finding of prima facie obviousness

Rational and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use an ester of conjugated linoleic acid, as suggested by Horrobin et al., in the method of treating rheumatoid arthritis as taught by Cook et al. and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Horrobin et al. suggests that esters of conjugated linoleic acid can be used in a method of treating rheumatoid arthritis. "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980)A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (In re Opprecht 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); In re Bode 193 USPQ 12 (CCPA) 1976).

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

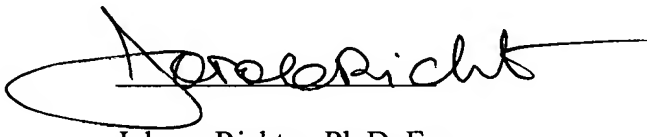
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst Arnold
Patent Examiner
Technology Center 1600
Art Unit 1616



Johann Richter, Ph.D. Esq.
Supervisory Patent Examiner
Technology Center 1600